USAID MEDICINES, TECHNOLOGIES, AND PHARMACEUTICAL SERVICES (MTAPS) PROGRAM

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A client picks up a prescription at a private-sector drug shop in Dhaka, Bangladesh. Photo credit: Raian Amzad, MSH

Regulatory Workforce Competency Mapping for National Regulatory Authorities in the Asia Region

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USAID MTaPS' support to national regulatory authorities (NRAs) in Bangladesh, Nepal, and the Philippines has led to structured capacity strengthening and development of comprehensive training plans.

Background

National regulatory authorities (NRAs) are responsible for ensuring the safety, efficacy, and quality of medical products and health technologies by fulfilling various functions, including product registration, licensing of establishments, regulatory inspections, vigilance, and clinical trials oversight. Medical products regulation requires critical technical skills and specialized knowledge that enable NRAs to meet their obligations and mandates. These skills and their application greatly impact the maturity level of NRAs, i.e., their capability to effectively regulate medical products in the market. The World Health Organization (WHO) Global Benchmarking Tool (GBT) provides a global metric that allows WHO and regulatory authorities to assess the overall maturity of a regulatory system on a scale of 1 (existence of some elements of regulatory system) to 4

(operating at advanced level of performance and continuous improvement). To support improvement in the maturity level of member states as per the WHO GBT, competency mapping helps identify existing gaps and weaknesses in the implementation of regulatory functions and informs requisite strategies to build capacity of the NRA regulatory workforce.

The WHO global competency framework is designed to identify critical gaps in the professional development and capacity of regulatory personnel. It provides performance indicators across a variety of national regulatory functions, including the regulatory framework, marketing authorization, inspection, vigilance, and laboratory analysis. It also allows competency modeling by individual NRAs across the maturity levels, particularly levels 1 to 3, aligning individual capabilities with organizational strategy and business processes. The framework is organized around the competencies of an individual regulatory professional regarding defined practice activities and can be used to define staff responsibilities. These practice activities are observable regulatory work inputs and outputs, and they integrate multiple competencies as well as the knowledge, skills, and behaviors for each activity. Practice activities are either core activities that are linked to the organizational regulatory system as defined in the WHO GBT, or are role-specific practice activities for reviewers, vigilance professionals, laboratory analysts, and inspectors.

The US Agency for International Development (USAID) Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program supports regional and country efforts in Asia under the Asia Bureau portfolio to strengthen medical products regulatory systems with a goal of improving access to quality-assured, safe, and effective medicines and other medical products and ensuring their appropriate use. One key area of support is strengthening the capacity of the regulatory workforce through competency mapping aligned to the WHO global competency framework.

Problem Statement

NRAs in low- and middle-income countries (LMICs) do not possess adequately structured and well-resourced regulatory frameworks to promote optimal access to medical products. In addition, there are gaps in regulatory knowledge, capacity to employ regulatory science, policy innovation, and skilled personnel, which has led to low maturity ratings as per the WHO GBT.

The regulatory capacity of NRAs across the Asian region shows varying levels of maturity. Only 5 of the 48 NRAs in the Asia region are operating at ML3 and ML4 (Indonesia, Singapore, South Korea, Thailand, and Vietnam).[1] Although some successes have been documented, there is a need for substantial development in the pharmaceutical regulatory space in Asia.

Key areas of need for most NRAs include building their technical and institutional capacity in regulatory functions such as product registration, regulatory inspections, and vigilance; instituting mechanisms to recognize and leverage decisions from functional NRAs by applying good reliance practices; enhancing coordination among regulators; promoting convergence toward regulatory harmonization; and adopting regionally endorsed standards and guidelines. One key limiting factor identified during NRA GBT assessments is the limited number of regulatory personnel with the appropriate competencies to effectively perform regulatory functions. To address NRA competency shortfalls and improve regulatory capacity, it is necessary to map existing competencies and take appropriate steps toward addressing these gaps.

Technical Approach

MTaPS provided technical assistance in the implementation of regulatory system–strengthening activities, including regulatory competency mapping, aimed at strengthening the capacity of NRAs at the institutional and individual levels. MTaPS successfully employed a mix of approaches: 1) regionally led approaches through networks such as South-East

[1] List of NRAs operating at ML3 and ML4 https://www.who.int/publications/m/item/list-of-nras-operating-at-ml3-and-ml4

Asia Regulatory Network (SEARN) and the Association of Southeast Nations (ASEAN) and 2) a bottom-up approach, whereby MTaPS worked directly with NRAs from select countries (i.e., Bangladesh, Nepal, and the Philippines) to implement regulatory capacity–strengthening activities locally, and thereafter convened regional networks to learn and share experiences.

Stakeholder Engagement

To strengthen the regulatory workforce in Asia, MTaPS partnered with the Nepal Department of Drug Administration (DDA), the Bangladesh Directorate General of Drug Administration (DGDA), and the Philippines Food and Drug Administration (FDA) to plan and conduct competency mapping exercises, support the dissemination of findings and recommendations, and validate results.

Intervention

MTaPS, in collaboration with the NRAs of Bangladesh, Nepal, and the Philippines, identified key regulatory areas and undertook competency mapping exercises using a questionnaire developed from the WHO global competency framework and implementation tools aligned to each country's needs (figure 1). The personnel assessed were those working in areas outlined in the competency framework and included functional areas of regulatory reviewers, inspectors, vigilance personnel, and analysts.

The objectives of the competency mapping were to:

- Identify gaps in critical skills, personnel experience and competencies of NRA staff in Bangladesh, Nepal, and the Philippines.
- Establish a framework that can be used to identify training needs and formulate plans to meet the requirements for each NRA to achieve its goal of increasing its regulatory maturity level.
- Guide regulatory staff training (academic and on-the-job training) to ensure systematic professional staff development (i.e., recruitment, development, and retention) and recognition.
- Develop a regional framework for capacity-strengthening activities in the Asia region that could be supported by partners and used by NRAs on a regular basis to measure progress.

Figure 1. Sample Questionnaire

Competency Domain	Competency Description	Behavior Testimony	Response	Comments
Bioavailability / bioequivalence	Apply scientific principles, regulatory requirements, and best practices to review bioavailability and bioequivalence data.	Do you articulate the historical background to bioequivalence requirements?	☐ Yes ☐ No ☐ N/A	
		Do you Articulate the responsibilities of sponsors in a bioequivalence study?	☐ Yes ☐ No ☐ N/A	
		Do you Assess in vitro dissolution study protocols and reports/results in line with applicable regulatory requirements (WHO or Ich requirements)?	☐ Yes ☐ No ☐ N/A	
		Do you Describe the key principles in bioanalytical methods for the analysis of subject samples?	☐ Yes ☐ No ☐ N/A	
		Do you Discuss the key pharmacokinetic parameters in the demonstration of Bioequivalence?	☐ Yes ☐ No ☐ N/A	
		Do you Explain the basic principles of equivalence and its application in BE studies?	☐ Yes ☐ No ☐ N/A	
		Do you Explain the basic principles of equivalence and its application in BE studies?	☐ Yes ☐ No ☐ N/A	
		Do you Explain the critical	☐ Yes ☐ No ☐ N/A	

The following areas, as illustrated in figure 2, were covered in the mapping exercise:

1. Organizational requirements

Meta-competencies: These competencies are essential for the whole organization's work environment and essential to performing specific regulatory functions. They form the foundation for organizational success and include the following aspects: communication, compliance, critical and analytical thinking, evidence-informed practice, lifelong learning, operating with integrity, problem-solving, production of results, and teamwork.

1.1 **Core organizational activities:** These activities are required for the regulation of medical products and are common to all regulatory functions in this domain. These include leadership; organizational awareness; preparation of reports to support regulatory decisions; quality management system (QMS); regulatory framework, policies, and process; surveillance and enforcement; and talent development.

1.2 **Core knowledge and skills:** These are knowledge and skills that support the core activities aligned to each regulatory function and are specific to that function.

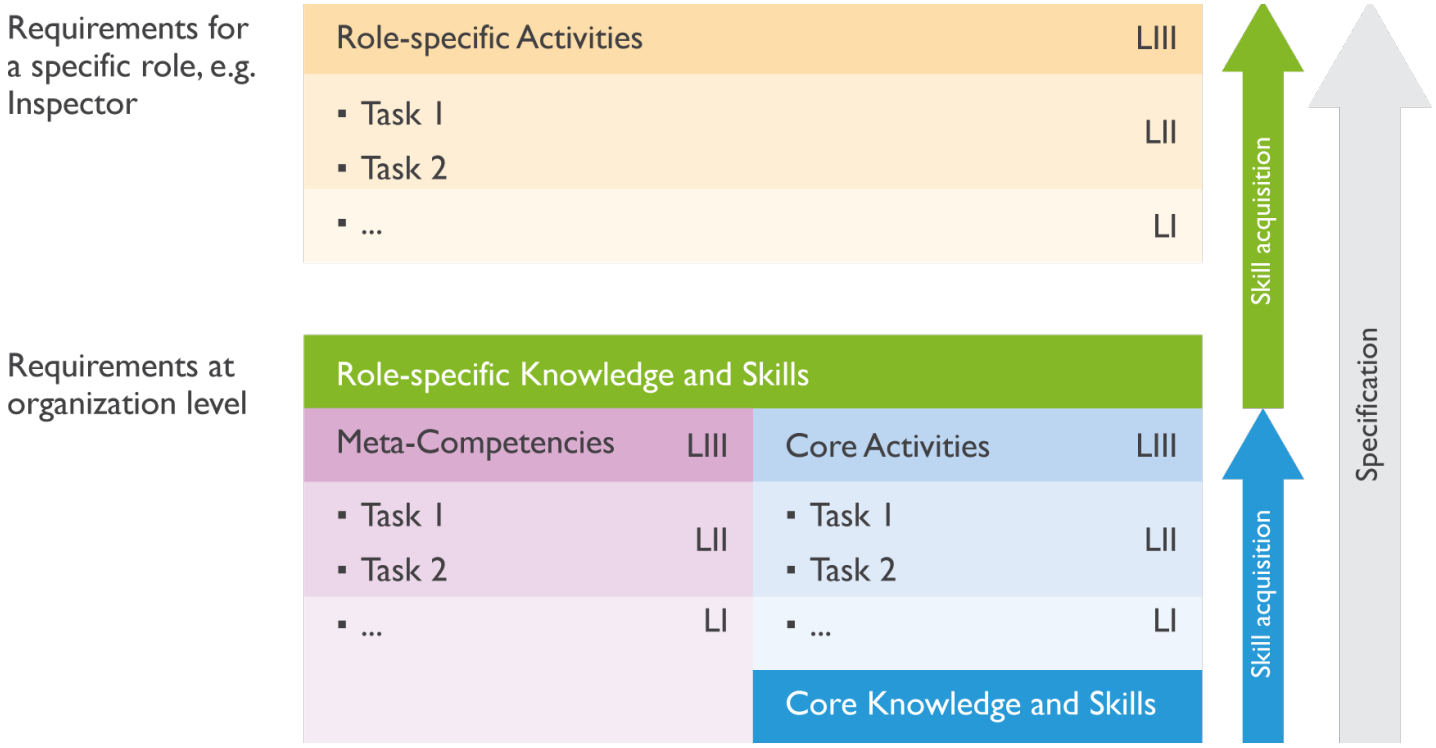
1.3 **Functional competencies:** These are competencies that underpin the understanding of the role of the NRA in terms of regulations including the statutes, guidelines, and processes, supervision of others, quality management system, regulatory inspections, and product quality.

2. Individual role-specific requirements

2.1 **Role-specific activities:** These tasks are specific to a regulatory role, which contribute to the NRA's regulatory functions.

2.2 **Role-specific knowledge and skills:** These knowledge and skills underpin the performance of role-specific practice activities.

Figure 2. Competency model for the regulation of medicines From WHO 2023. Global competency framework for regulators of medicines. https://iris.who.int/bitstream/handle/10665/374053/9789240078758-eng.pdf?sequence=1



A scoring system was assigned to each of the responses in the questionnaire, as shown in table 1. The scoring system and questions are based on three proficiency levels—foundation, intermediate, and advanced—with each level assigned a proficiency number, which was concealed during the administration of the questionnaire. The proficiency levels were then categorized into activity achievement scores (i.e., initiated, partially implemented, and implemented) based on responses to proficiency-level questions in the questionnaire. The scoring was done according to each competency domain, which is a set of related foundational technical abilities representing required elements and outcomes that define knowledge, skills, experience, and behaviors. The score for each competency domain was the total score of all the responses to the questions in that domain and was calculated as outlined in table 1. In addition, each of the competency domains received a percentage score achieved against the expected score. The score denominator was the total expected score for the domain. The expected score was achieved by multiplying the proficiency number and the highest assigned number under the fully implemented activity score level for foundation, intermediate, and advanced levels of complexity. In table 1, for example, the expected score for foundation level fully implemented is 30 (3x10); for intermediate fully implemented, 60 (6x10); and for advanced fully implemented, 90 (9x10). The total achieved score served as the numerator while expected total score served as the denominator for the percentage scores for each domain.

Workshop sessions were facilitated virtually and in person by MTaPS' country and regional teams during the data collection phase with relevant NRA staff using the questionnaires. MTaPS teams recorded the responses and deliberations and captured all the responses in the questionnaire. The relevant documents, including standard operating procedures (SOP) and policies, among others, were provided by the NRA staff to substantiate the responses where applicable. NRA teams submitted section-specific responses for technical evaluation validation and analysis by MTaPS. MTaPS then organized dissemination workshops to share findings with the NRAs and incorporated inputs and feedback into the final report.[2]

Table 1. Scoring system for individual responses by proficiency level for each competency

Serial. No.	Proficiency Level	Assigned Proficiency Number	Activity achievement score	Assigned number	Lowest Score	Highest Score
1	Foundation	3	Initiated/preliminary stage	1–3	3	9
			Partially implemented	4–6	12	18
			Implemented/in practice	7–10	21	30
2	Intermediate	6	Initiated/preliminary stage	1–3	6	18
			Partially implemented	4–6	24	36
			Implemented/in practice	7–10	42	60
3	Advanced	9	Initiated/preliminary stage	1–3	9	27
			Partially implemented	4–6	36	54
			Implemented/in practice	7–10	63	90

[2] Of the three countries, only the Nepal Department of Drug Administration (DDA) did not undergo competency mapping for the regulatory function of laboratory investigations because the laboratory analysis department is currently not part of the DDA.

Results and Achievements

Practice/Core Activities for Bangladesh, Nepal, and the Philippines

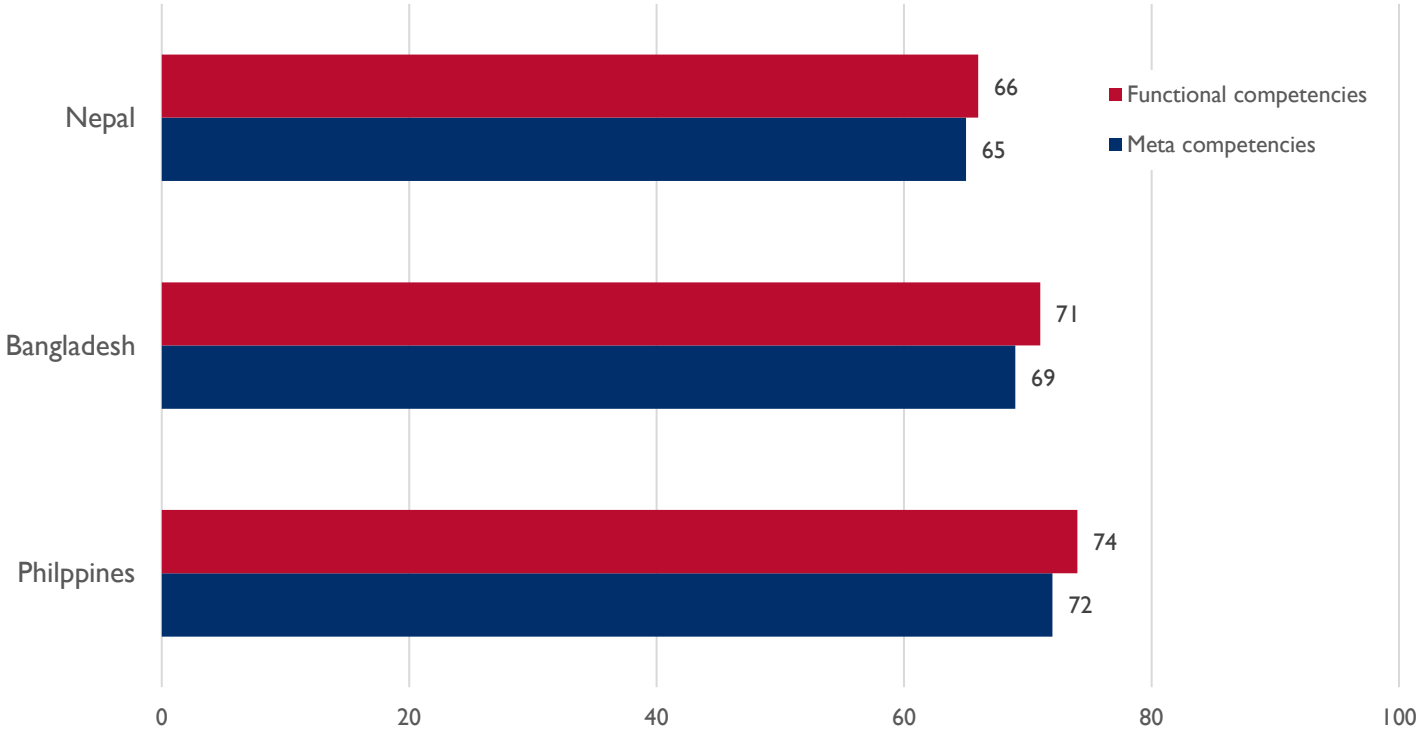
The competency levels for the three countries demonstrate good understanding, knowledge, skills, and practices in undertaking regulatory activities across the various competency areas. Even so, there are critical areas that need to be developed and improved in terms of skills, knowledge, and practice, as well as the systems required to address these areas. This includes pharmacovigilance and the patient safety system, especially in areas of risk management and signal detection; reviewing data on safety and efficacy; the validation process for reviewers; and method transfer for analysts. The findings highlight varying degrees of the regulatory environment and the development required for the adequate regulation of health products and subsequent levels of maturity as seen in the core organizational practice areas. Overall, the Philippines FDA has appreciably better competencies in the core practice areas. On average, the pharmacovigilance function across all three countries was the area with the lowest performance of existing skills and competencies, while reviewers' functions were most developed in terms of process documentation, decision making, and communication.

Meta and Functional Competencies for Bangladesh, Nepal, and the Philippines

Figure 3 represents meta and functional competencies—these are essential for the whole organization's work environment and for performing the specific regulatory functions. These competencies form the foundation for organizational success and are essential for successful regulation. The results show a need to improve several of these functions that underpin the regulatory system in terms of communication, compliance, critical and analytical thinking, evidence-informed practice, lifelong learning, operating with integrity, problem-solving, production of results, and teamwork.

Figure 3 also presents functional competencies, which underpin the understanding of each role of the various functions of NRAs in terms of regulations, including statutes, regulations, guidelines, and processes. There is a good understanding of the regulatory environment, and personnel in each functional area have a good grasp of their roles and responsibilities; however, it is necessary to continue strengthening capacity and levels

Figure 3. Findings of meta and functional competencies for Bangladesh, Nepal, and the Philippines



of knowledge and expertise within the organizations for these roles. The results show a close correlation between these two competency areas that highlight the processes within the organization and the understanding and application of these processes. However, both meta and functional competencies are still at around 70%–75% on average, and there is a need for improvement to attain excellent understanding, which is marked by a score of 80% and above.

Role-Specific Requirements for Bangladesh, Nepal, and the Philippines

The findings presented in figure 4 show results for each of the regulatory functional areas in terms of individuals' skills, knowledge, abilities, and experience in carrying out tasks specific and relevant to that function. For example, inspectors undertake various tasks, including clinical study operations (good clinical practices [GCP]), inspections, data management, and informatics, ensuring product quality and recommending and enforcing regulatory actions. Reviewers undertake activities that include performing reviews for bioavailability (BA), bioequivalence (BE), safety and efficacy data, investigational product development, and ethical considerations. Vigilance tasks include post-market surveillance, safety data collection and review, medication error reporting, and risk-benefit evaluation, while analysts carry out work that includes investigations of noncompliance, validation process and method transfer, performing mathematical manipulations, and performing measurements/tests/assays, among others. The results show a need for the development of capacities and skills across all the areas, especially in the reviewer and vigilance functions, as well as in several aspects of inspections, particularly GCP inspections. Analysts need to strengthen their capacity in investigating noncompliance and method transfer.

Figure 4. Findings for role-specific requirements for Bangladesh, Nepal, and the Philippines (percentage)

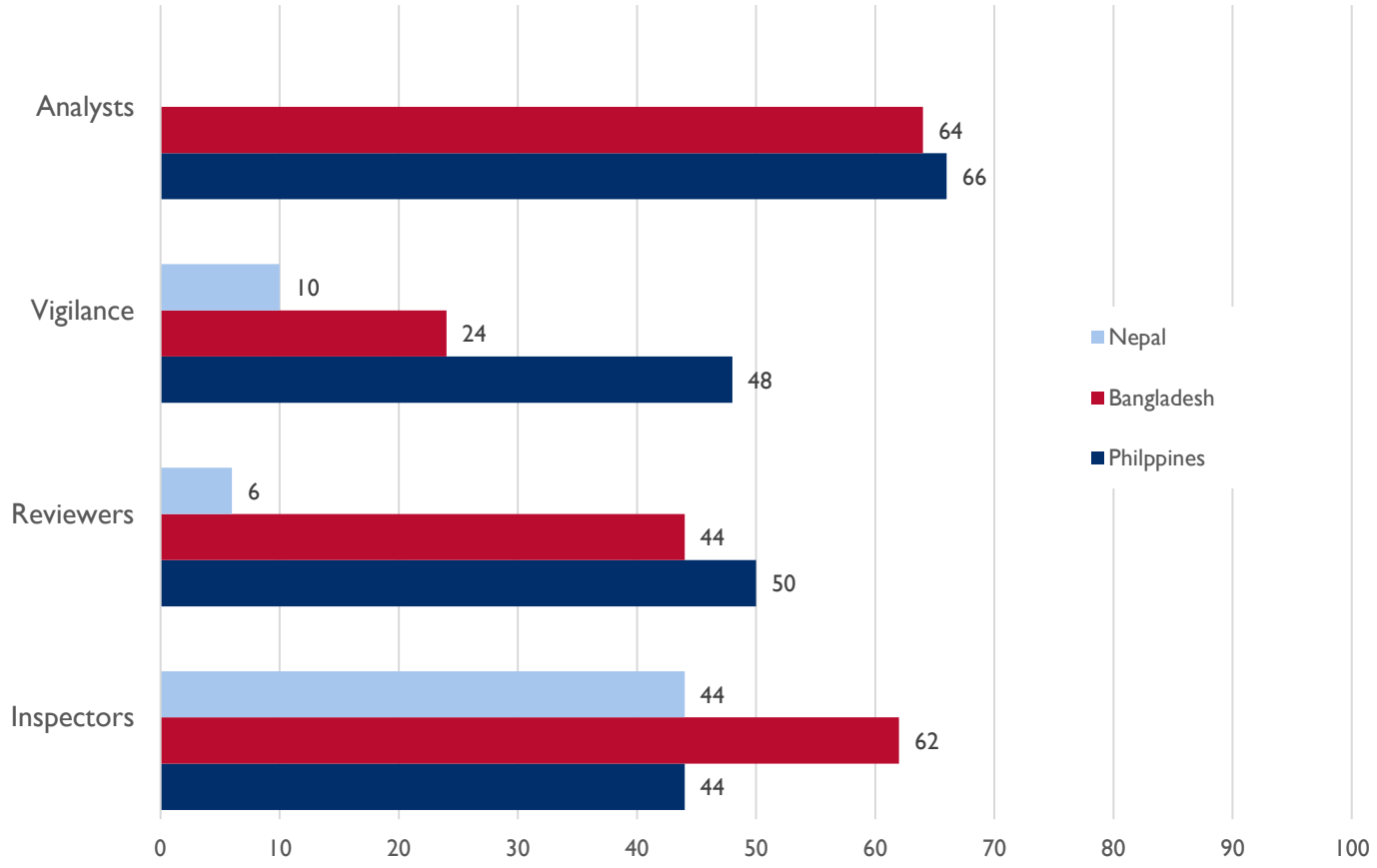


Table 2. Immediate priorities for regulatory authorities in Bangladesh, Nepal, and the Philippines

Competency Domain	Processes and Tools	Training/Improving Competency
5.1 Practice activities—core	Leadership	Leadership, and management training for all top leaders, unit heads, directors, and senior managers
	QMS implementation	Training on all aspects of QMS for effective implementation, including principles of QMS, risk management, internal audit, and QMS for lead auditors
	Regulatory framework, policies, regulations	Demonstration and training on good regulatory practices
	Talent development	Development of individual training plan for each regulator
5.3 Practice activities—reviewers	Maintains a register of approved products	Training on all current regulations, guidelines, and procedures for registration of medical products
	Makes or recommends regulatory decisions	Management for senior managers in registration department
	Manages the product review system	Training on good review practices and good reliance practices
	Reviews data on safety, efficacy, and quality	Training on evaluation of product dossiers for generic medicines, using common technical document (CTD) guidelines, assessment of BE/BA studies, and assessment of the active pharmaceutical ingredients section of CTD dossier
5.4 Practice activities—inspectors	Develops checklist and SOP for good manufacturing practice (GMP) inspections	Training on current regulatory compliance based on GMP guidance
	Develops procedure for delegation of authority for regulatory decision (a checklist for this process)	Follow-up documentation to conform to the delegation of authority
	Develops policy, guideline, and SOP and confirms that the right skills are available	Selection of appropriate person with the organization and training on report writing and document management
	Develops SOPs and checklist and implement system for inspection of drug consignments and clinical research organization	Mock inspections for the inspectors at regular intervals and training on different types of inspection and good practices (good pharmacy practices, good distribution practices, GCP, GMP)

Based on the assessment conducted, the immediate priorities for the regulatory authorities were identified and summarized in table 2. These recommendations were based not only on the score achieved, but also considering the priority areas for skill development in line with the WHO GBT maturity levels 3 and 4, which apply across the three countries.

Conclusion

Competency mapping is an important intervention for identifying areas of competency, knowledge, and skill gaps in regulatory authorities. Due to the COVID-19 pandemic and differences in country contexts, MTaPS adapted the implementation plan, for example, by using virtual data collection and customizing support to the organizational structures of NRAs. MTaPS worked with the NRAs to use the results from competency assessments to inform the process of supporting the development of training plans. NRAs can utilize their training plans to increase individual, team, and organization-wide competencies and thereby improve performance of their regulatory functions. These improvements can have cascading effects in ensuring that medical products are safe, effective, affordable, and of high quality.

MTaPS will support countries to undertake the following key next steps:

- Implement capacity-strengthening training identified in the training plans.
- Develop regional guidance on how to address the training needs that were identified during the competency mapping to improve skills and knowledge and to build experience necessary for the regulatory workforce.
- Develop a regional capacity-building strategy in partnership with SEARN.

Recommendations

For NRAs:

- Identify opportunities for skills development based on the gaps identified by competency mapping exercises and outlined in the training plans.
- Continue to build strong foundations in regulatory competency by implementing and tracking WHO GBT indicators while collaborating with external organizations, and planning for the short-, middle-, and long-term interventions.
- Implement a talent development plan that connects talent needs with resources and that recruits, retains, manages, and nurtures regulatory personnel.

For regional networks:

- Develop regional capacity-building guidance for countries to adopt and implement.
- Develop quality documentation management systems as an outcome of the mapping exercise.

Pharmacy in Kathmandu, Nepal. Photo credit: MTaPS

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About USAID MTaPS:

The USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program (2018–2025) enables low- and middle-income countries to strengthen their pharmaceutical systems, which is pivotal to better health outcomes and higher-performing health systems. The program is implemented by a consortium of global and local partners, led by Management Sciences for Health (MSH), a global health nonprofit.